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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): A03P3004-US1

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on E-FILED

Signature 7-22-08

Typed or printed name ESTHER CAMPBELL

Application Number	Filed
10/674,710	9-29-03

First Named Inventor: TURCOTT

Art Unit	Examiner
3762	SMITH

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 46,941

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Theresa Takeuchi
Signature

THERESA TAKEUCHI
Typed or printed name

408-522-6167
Telephone number

7-22-2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 2 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: Smith, Terri L.
Robert G. Turcott	Art Unit: 3762
Application No.: 10/674,710	Confirmation No.: 4592
Filed: September 29, 2003	Docket No.: A03P3004-US1
For: System and Method for Rapid Optimization of Control Parameters of an Implantable Cardiac Stimulation Device	

Mail Stop **AF**
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

ARGUMENTS TO ACCOMPANY THE PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

Applicant hereby submits the following Arguments as an attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33). A Notice of Appeal is filed concurrently herewith.

Summary Of Request

Applicant respectfully submits that the outstanding rejections of the claims pending in the above identified application are improper and without legal or factual basis. Applicant further submits that the outstanding rejections can be readily reviewed and summarily resolved in light of the present record. Accordingly, Applicant requests review of the outstanding rejections pursuant to a pre-appeal conference.

In the Office action dated April 22, 2008, which was made final, the Examiner rejected claims 1, 4-8, and 12-23 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,487,752 to Salo et al. Claims 1, 4, 5-8 and 12-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,643,327 to Dawson et al.

Applicant's claimed invention, as recited in independent claim 1 is directed toward a method for identifying preferred control parameters for use in controlling an implantable cardiac stimulation device, the method comprising the steps of controlling the device to deliver therapy to the heart of the patient during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters. Neither Salo et al. nor Dawson et al. disclose or suggest controlling an implantable device to deliver therapy to the heart of the patient during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters. Accordingly, without more evidence of unpatentability, Applicant is entitled to grant of a patent and therefore respectfully requests that presently pending claims 1, 2, 4-8, and 10-23 be promptly allowed.

Argument

The Examiner's April 22, 2008 Office Action is the fifth Office Action Applicant has received to date in response to their application for a patent. With respect to Applicant's pending claims 1, 2, 4-8, and 10-23, the April 22, 2008 Office Action maintains the Examiner's previous rejections in the February 14, 2007 Office Action.

The Salo reference teaches a method of optimizing an intrinsic cardiac performance parameters of a heart, wherein a paced A-V interval is changed for a **relatively few beats**, e.g., 5 beats, and **then allowed to return to a baseline value for a relatively long time**, e.g., 20 beats. Salo, Col. 3, ll. 47-55. Contrary to the Examiner's statement otherwise, Salo et al. do not teach or disclose "controlling an implantable device to deliver therapy to the heart of the patient during a series of consecutive evaluation periods that are substantially **equal in duration** to one another and **less than about 12 seconds each** in duration **by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters**," as required by claim 1.

It is the Examiner's position that Salo discloses switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration. The Examiner cites Figs. 2-3 and 5, col. 3, ll. 51-54 and asserts that 5 beats is approximately 5 seconds and asserts that switching among sets of control parameters is the different intervals shown in blocks 40 and 44 of Fig. 5 of Salo. The Examiner further points to Fig. 3 and blocks 42, 44, 46, and 48 of Fig. 5 as disclosing altering from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters.

However, Fig. 3 of Salo depicts paced evaluation periods of 5 beats immediately followed by baseline evaluation periods of 20 seconds. Similarly, in Fig. 5, block 42, Salo discloses determining a baseline value of a cardiac performance parameter **for a first time period,** and in block 44 Salo discloses pacing a heart at a selected modified cardiac cycle parameter for a second time period **less than the first time period**. In block 52 of Fig. 5, Salo teaches waiting a predetermined time period between modification of cardiac cycle parameters. At Col. 5, ll. 42-53, Salo states:

> Next, at decision block 50, controller 30 determines if **further short series of pacing cycles** with modified A-V delays are to be tested and the resulting cardiac output measurements determined and stored. If there are more pacing cycles to be executed, the algorithm proceeds to block 52 where controller 30 **waits** a predetermined period of time, preferably **20 beats**, as shown in FIG. 3, **and then** again paces the heart at the next selected modified pacing cycle parameter for a **short** period of time associated with **five successive beats**. (emphasis added).

Further, Salo specifically teaches maintaining a 4:1 ratio between the paced evaluation period and the baseline evaluation period (Salo, Col. 4, ll. 1-4) and that the short pacing intervals are separated from one another by a relatively long, programmable period of time. Col. 5, ll. 60-62. Thus evaluation periods disclosed in Salo are not substantially equal in duration and the baseline evaluation period is not less than about 12 seconds, as required by claim 1.

The Dawson reference teaches a method of optimizing cardiac performance parameters of a heart by measuring a parameter indicative of the volume of blood in

a heart chamber (e.g., PDI) as a function of a pacing parameter (e.g., A-V delay). Dawson, Abstract. The A-V delay is adjusted within the pacemaker to conform to the optimized volume parameter, i.e., minimum acceptable PDI value. Dawson, col. 2, ll. 64-66. Contrary to the Examiner's statement otherwise, Dawson et al. do not teach or disclose "controlling an implantable device to deliver therapy to the heart of the patient during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration **by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters**," as required by claim 1.

The Examiner cites Fig. 1, element 1, and Figs. 7A-7B, col. 6, ll. 51-53 and 63-65 of Dawson as disclosing controlling an implantable device to deliver therapy to the heart of a patient while switching among sets of control parameters during a series of consecutive evaluation periods that are substantially equal in duration to one another and less than about 12 seconds each in duration.

However, the cited portion of Dawson fails to disclose alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters, as required by claim 1. Instead, the cited sections of Dawson disclose only altering between test parameters. The heart is paced at a preset A-V delay, the corresponding PDI parameter is calculated, it is determined whether the PDI is stable. If the PDI is stable the A-V delay is increased until the A-V delay is at a maximum. Dawson, Col. 6, ll, 50-64 and Fig. 7A.

In Fig. 7B, as described in Col. 7, ll. 31-54, Dawson discloses using a fusion knee point to determine the optimum A-V delay. Dawson teaches taking points along the curve 108 (having two portions 108A, corresponds to the smaller A-V delay values and having a relatively low absolute slope and a second portion, 108B, corresponding to the larger A-V delay values, and having a larger absolute slope) and extrapolating the slopes between adjacent points. Dawson further discloses another method of determining the fusion knee by determining the natural A-V duration of the patient and estimating the fusion knee point C to be slightly longer than this natural A-V duration. Dawson teaches that beyond the knee point C, the

PDI value has no practical meaning and thus the A-V delay is set in step S216 to a value which is slightly smaller than the position of the fusion knee. Thus Dawson does not teach or suggest alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters, but instead teaches pacing only at increasingly longer A-V delays until either the PDI is unstable or the A-V delay is at a maximum.

Applicants therefore submit that independent claim 1 and claims 2, 4-8, and 10-23 which depend therefrom, are patentable over the cited art.

Conclusion

Applicant submits that Salo and Dawson do not therefore disclose each and every element as set forth in Applicant's claimed invention and do not therefore anticipate Applicant's claimed invention. Applicant therefore submits that the Examiner's continued reliance on Salo and Dawson to support an anticipation rejection of the currently pending claims is improper. Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration of Applicants' Pre-Appeal Brief Request for Review is respectfully requested.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 22-0265.

Respectfully submitted,

Dated: 7/21/08

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